EXHIBIT 412

RITE AID DISTRIBUTION CENTER DEA REGULATORY GUIDELINES



DISTRIBUTION / CUSTOMER SUPPORT CENTER PRESCRIPTION DRUG SOPS

REGULATORY GUIDELINES

POLICY

RITE AID is committed to meeting the legal and regulatory requirements of those locations where the company conducts operations. In the case of drug substances and products regulated as Controlled Substances and chemicals regulated as Listed chemicals by the U.S. Drug Enforcement Administration (DEA), it is the policy of RITE AID to apply these requirements to all operations where such drug substances, drug products and Listed chemicals are manufactured, packaged, and/or distributed.

Therefore, the following DEA REGULATORY GUIDELINES were prepared in response to a need for a single source of current information for RITE AID regarding Drug Enforcement Administration (DEA) policies and the requirements of the Comprehensive Drug Abuse Prevention Act (Public Law 91-5132), otherwise known as the Controlled Substances Act of 1970 (CSA) and the implementing regulations.

The CSA and its' regulations affect every aspect of a DEA registrant's ordering, receiving, storage, returns to the supplier, and disposal of products that contain Controlled Substances or List I chemicals. Because the vast majority of all legitimate medical use of Controlled Substances at some point passes through a distributor, this represents a major focus of DEA enforcement attention and investigative activity.

If violations are discovered by the DEA, administrative, registration, civil, or criminal actions are considered and may be applied. The CSA and the implementing regulations and the DEA's enforcement of them are so strict that there can be DEA actions even for recordkeeping violations in the absence of any evidence of diversion.

RITE AID is responsible for ensuring compliance with DEA regulatory requirements, and that responsibility for compliance cannot be abdicated or transferred to anyone else. The legislative and social intent of regulating Controlled Substances and products that contain List I chemicals is consistent with the mission of RITE AID in serving the public good. To achieve these important goals, RITE AID supports the proper and appropriate use of Controlled Substances and products that contain List I chemicals for legitimate use and seeks to eliminate any and all diversion of Controlled Substances and products that contain List I chemicals.

In order for RITE AID facilities to ensure that they are in full compliance with DEA requirements, RITE AID facilities will undertake selected internal reviews to assure regulatory compliance and compliance with DEA requirements. The more frequently all aspects of DEA compliance are reviewed, the better the chances that RITE AID will be in compliance and not experience problems when DEA or others review our operation.

Site Administration

Each RITE AID registrant handling Controlled Substances will designate a DEA Coordinator or DEA Point Person. The DEA Coordinator/Point Person will implement the required systems and procedures and ensure that RITE AID site operations are consistent with the DEA REGULATORY GUIDELINES.

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I. GLOSSARY

A. CONTROLLED SUBSTANCES

Definitions Relating To Controlled Substances (Reference is made to Sec. 1300.01 Code of Federal Regulations, Food and Drugs 21 Part 1300 to End, Revised as of April 1, 2000) and the Controlled Substances Act (CSA). Please refer to the CSA and the implementing regulations for additional information.

- 1. Act means the Controlled Substances Act, as amended (84 Stat. $\overline{1242}$; 21 U.S.C. 801) and/or the Controlled Substances Import and Export Act, as amended (84 Stat. 1285; 21 U.S.C. 951). This is the authority that the DEA operates under.
- 2. Administration means the Drug Enforcement Administration $\overline{\text{(DEA)}}$. The DEA is an administration within the Department of Justice.
- 3. Administrator means the Administrator of the Drug Enforcement Administration. The Administrator has been delegated authority under the Act by the Attorney General (28 CFR 0.100).
- 4. Agent means an authorized person who acts on behalf of or at the direction of a manufacturer, distributor or dispenser (DEA registrants).
- 5. Anabolic Steroid means any drug or hormonal substance, chemically and pharmacologically related to testosterone (other than estrogens, progestins and corticosteroids) that promotes muscle growth.
- 6. ARCOS Automation of Reports and Consolidated Order Systems.

 ARCOS reporting is required for U.S. manufacturers, repackers/relabelers of bulk or finished dosage forms for all Schedule I or II compounds, narcotic Schedule III and psychotropic Schedule III and IV compounds and for distributors of Schedule I and II and narcotic Schedule III compounds.
- 7. Basic Class is a term that refers to Controlled Substances listed in Schedules I and II.
- 8. Commercial container means any bottle, jar, tube, ampule, or other receptacle in which a substance is held for distribution or dispensing to an ultimate user, and in addition, any box or package in which the receptacle is held for distribution or dispensing to an ultimate user. The term commercial container does not include any package liner, package insert or other material kept with or within a

commercial container, nor any carton, crate, drum, or other package in which commercial containers are stored or are used for shipment of Controlled Substances.

- 9. Controlled Substance has the meaning given in section 802(6) of Title 21, United States Code (U.S.C.).
- 10. Customs territory of the United States means the several States, the District of Columbia, and Puerto Rico.
- 11. DEA Regional Administrator "Special Agent in Charge"
 - a. DPM Diversion Program manager, located at the DEA divisional office.
 - b. DGS Diversion Group Supervisor, located at various DEA officers.
- 12. <u>Dispense</u> means to deliver a Controlled Substance to an ultimate user or research subject by the lawful order of a practitioner.
- 13. <u>Dispenser</u> means an individual practitioner, institutional practitioner, pharmacy or pharmacist who dispenses a Controlled Substance.
- 14. <u>Distributions</u> means by which perpetual inventory is change by any of the following means: Invoice, 106, 41, Return to Vendor or sent to Reverse Distributor.
- 15. Distributor means a person who forwards a controlled substance, List I Chemical and/or a product that contains a List I chemical through authorized/legitimate channels. A distributor may not relabel or repackage the products from the original labeled commercial container that holds the product received from their vendor, prior to distribution. A distributor may only ship the drugs for distribution, in its' original labeled commercial container by securing into a shipping container, FedEx box, UPS package, etc.
- 16. <u>Diversion</u> means the unauthorized removal of Controlled Substances or List I chemicals from the approved distributed chain.
- 17. Export means with respect to any article, any taking out or removal of such article from the jurisdiction of the United States (whether or not such taking out or removal constitutes an exportation within the meaning of the customs and related laws of the United States).
- 18. Exporter includes every person who exports, or who acts as an export broker for exportation of, Controlled Substances listed in any schedule.

19. Freight forwarding (as used in DEA's regulatory meaning does not have the same meaning that it carries in the transportation/distribution industry). Means a separate facility operated by a distributing registrant through which sealed, packaged Controlled Substances and listed chemicals in unmarked shipping containers (i.e., the containers do not indicate that the contents include Controlled Substances) are, in the course of delivery to or return from customers, transferred in less than 24 hours. A distributing registrant who operates a freight forwarding facility may use the facility to transfer Controlled Substances from any location the distributing registrant operates that is registered with the DEA to manufacture, distribute, or import Controlled Substances, or, with respect to returns, registered to dispense Controlled Substances, provided that the notice required by Section

For purposes of this definition, a distributing registrant is a person who is registered with the DEA as a manufacturer, distributor, and/or importer.

1301.12(b)(4) of Part 1301 of this chapter has been submitted

- 20. Immediate Precursor means a substance which the Attorney General has by regulation designated as being the principal compound used or produced primarily for use in the manufacture of a Controlled Substance; is an immediate chemical intermediary used or likely to be used in the manufacture of such Controlled Substances; and the control of which is necessary to prevent, curtail or limit the manufacturer of such Controlled Substance.
- 21. Import means, with respect to any article, any bringing in or introduction of such article into either the jurisdiction of the United States or the customs territory of the United States, and from the jurisdiction of the United States into the customs territory of the United States (whether or not such bringing in or introduction constitutes an importation within the meaning of the tariff laws of the United States).
- 22. <u>Importer</u> includes every person who imports, or who acts as an import broker for importation of, Controlled Substances listed in any schedule.
- 23. Individual Practitioner means a physician, dentist, veterinarian or other individual licensed, registered or otherwise permitted by the U.S., or the jurisdiction in which he/she practices; to dispense a Controlled Substance (does not include a pharmacist, pharmacy or an institutional practitioner).
- ${1\over 24}$. Initial Inventory Date means the date activities with Controlled Substances begin (not the date of registration or

and approved.

- date of application for registration).
- 25. <u>Institutional Practitioner</u> means a hospital or other person licensed, registered or otherwise permitted, by the U.S. or jurisdiction in which it practices, to dispense a Controlled Substance.
- 26. Inventory means all factory and branch stocks in finished form of a basic class of Controlled Substance manufactured or otherwise acquired by a registrant, whether in bulk, commercial containers, or contained in pharmaceutical preparations in the possession of the registrant (including stocks held by the registrant under separate registration as a manufacturer, importer, exporter or distributor).
 - (a) Biennial Inventory means a physical inventory conducted on the initial inventory date and another within two years.
 - (b) Daily Use Inventories mean a physical inventory maintained for each controlled that list receipts, deductions and physical inventory on a daily basis.
 - (c) ARCOS Year Ending Inventory means that Manufacturers and distributors are required to report their annual inventories of specific controlled substances. The CFR requires that an **annual** inventory of each reportable controlled substance be taken on December 31st of each year and filed with DEA (ARCOS) **no later than**January 15th of the following year.
- 27. Isomer means the optical isomer, except as used in Sec. 1308.11(d) and Sec. 1308.12(b)(4) of the regulations. As used in Sec. 1308.11(d) of the regulations, the term isomer means the optical, positional, or geometric isomer. As used in Sec. 1308.12(b)(4) of the regulations, the term isomer means the optical or geometric isomer.
- 28. <u>Jurisdiction</u> means of the United States means the customs territory of the United States, the Virgin Islands, the Canal Zone, Guam, American Samoa, and the Trust Territories of the Pacific Islands.
- 29. <u>Label</u> means any display of written, printed, or graphic matter placed upon the commercial container of any Controlled Substance by any manufacturer of such substance.
- 30. <u>Labeling</u> means all labels and other written, printed, or graphic matter:
 - (a) Upon any Controlled Substance or any of its commercial containers or wrappers, or

- (b) Accompanying such Controlled Substance.
- 31. Manufacture means the producing, preparation, propagation, compounding, or processing of a drug or other substance or the packaging or repackaging of such substance, or the labeling or relabeling of the commercial container of such substance, but does not include the activities of a practitioner who, as an incident to his/her administration or dispensing such substance in the course of his/her professional practice, prepares, compounds, packages or labels such substance. The term manufacturer means a person who manufactures a drug or other substance, whether under a registration as a manufacturer or under authority of registration as a researcher or chemical analyst.
- 32. Methamphetamine Control Act (MCA) means the act establishing ephedrine, pseudoephedrine, phenylpropanolamine and combination ephedrine products as regulated List 1 chemicals, and requires that reports of certain distributions to non-regulated persons be reported each month.
- 33. Narcotic drug means any of the following whether produced directly or indirectly by extraction from substances of vegetable origin or independently by means of chemical synthesis or by a combination of extraction and chemical synthesis:
 - (a) Opium, opiates, derivatives of opium and opiates, including their isomers, esters, ethers, salts, and salts of isomers, esters, and ethers whenever the existence of such isomers, esters, ethers and salts is possible within the specific chemical designation. Such term does not include the isoquinoline alkaloids of opium.
 - (b) Poppy straw and concentrate of poppy straw.
 - (c) Coca leaves, except coca leaves and extracts of coca leaves from which cocaine, ecgonine and derivatives of ecgonine or their salts have been removed.
 - (d) Cocaine, its salts, optical and geometric isomers, and salts of isomers.
 - (e) Ecgonine, its derivatives, their salts, isomers and salts of isomers.
 - (f) Any compound, mixture, or preparation which contains any quantity of any of the substances referred to in paragraphs (b) (31) (i) through (v) of the regulations.
- 34. Net disposal means, for a stated period, the quantity of a basic class of Controlled Substance distributed by the

registrant to another person, plus the quantity of that basic class used by the registrant in the production of (or converted by the registrant into) another basic class of Controlled Substance or a non-Controlled Substance, plus the quantity of that basic class otherwise disposed of by the registrant, less the quantity of that basic class returned to the registrant by any purchaser, and less the quantity of that basic class distributed by the registrant to another registered manufacturer of that basic class for purposes other than use in the production of, or conversion into, another basic class of Controlled Substance or a non-Controlled Substance or in the manufacture of dosage forms of that basic class.

- 35. Opiate means any drug or other substance having an addition-forming or addition-sustaining liability similar to morphine or being capable of conversion into a drug having such addiction-forming or addiction-sustaining liability.
- 36. Opium Poppy means the plant of the species Pavaver somniferm L., except the seed thereof
- 37. Pharmacist means any pharmacist licensed by the State to dispense Controlled Substances, including any person authorized by a State to dispense Controlled Substances under the supervision of the licensed pharmacist.
- 38. <u>Person</u> includes any individual, corporation, government or governmental subdivision or agency, business trust, partnership, association, or other legal entity.
- 39. Primary Record a document designated for receiving or distribution that contains all information as required by the regulations.
- 40. <u>Prescription</u> means an order for medication dispensed to or for the ultimate user.
- 41. Poppy Straw means all parts, except the seeds, of the opium poppy, after mowing.
- 42. <u>Production</u> means the manufacture, planting, cultivation, growing, or harvesting of a Controlled Substance.
- 43. <u>Purchaser</u> means any registered person entitled to obtain and execute order forms pursuant to Section 1305.04 and Section 1305.06.
- 44. Quota means a quantitative expression of the amount of each Controlled Substance that may be produced during the calendar year. There are three types of quotas as follows:
 - (a) The aggregate production quota is a quantitative expression of the amount of each Controlled Substance

- that may be produced during the calendar year to provide for: the estimated medical, scientific, research, and the industrial needs for the U.S.; the lawful export requirements; and the establishment and maintenance of reserve stocks.
- (b) The manufacturing quota is the quantity of Controlled Substances which an individual manufacturer may produce during the calendar year. Manufacturing quotas are determined on the basis of the manufacturer's estimated disposal inventory and other special requirements. Additional factors considered are the manufacturer's current rate of disposal, the trend of the national disposal rate during the preceding calendar year, the production cycle, the inventory position as well as economic availability of raw materials, along with yield and stability problems. Emergencies also have an effect in the determination of the manufacturing quota.
- (c) Procurement quotas are issued annually by the "share-of-the-market theory" to the various procurement quota applicants. Share-of-the market is determined by calculating the percentage of business a firm did in a particular basic class the previous year as compared to the total disposal of all the firms utilizing that same basic class.
- 45. Readily retrievable means that certain records are kept by automatic data processing systems or other electronic or mechanized recordkeeping systems in such a manner that they can be separated out from all other records in a reasonable time and/or records are kept on which certain items are asterisked, redlined, or in some other manner visually identifiable apart from other items appearing on the records.
- 46. Register and registration refer only to registration required and permitted by sections 303 or 1007 of the Act (21 U.S.C. 823 or 957).
- 47. Registrant means any person who is registered pursuant to either section 303 or section 1008 of the Act (21 U.S.C. 823 or 958).
- 48. Schedule I Controlled Substances means a drug or substance that has a high potential for abuse, has no currently accepted medical use in treatment in the U.S., and lacks accepted safety under medical supervision. Listed in 21 CFR, Part 1308.11.
- 49. Schedule II Controlled Substances means a drug or substance that has a high potential for abuse, has a currently accepted medical use for treatment in the U.S., and abuse of the drug may lead to severe psychological or physical dependence. Listed in 21 CFR Part 1308.12.

- 50. Schedule III Controlled Substances means a drug or substance that has a potential for abuse less than the drugs listed in schedule I and II, has a currently accepted medical use in the U.S., and abuse of the drug may lead to moderate or low physical dependence or high psychological dependence. Listed in 21 CFR Part 1208.13.
- Schedule IV Controlled Substances means a drug or substance with a low potential for abuse relative to the drugs in Schedule III, has a currently accepted medical use in treatment in the U.S., and abuse of the drug may lead to limited physical or psychological dependence relative to the drugs in Schedule III. Listed in 21 CFR Part 1208.14.
- 52. Schedule V Controlled Substance means a drug or substance with low potential for abuse relative to the drugs in Schedule IV, has a currently accepted medical use in treatment in the U.S., and abuse of the drug may lead to limited physical or psychological dependence relative to drugs in Schedule IV. Listed in 21 CFR Part 1308.15.
- 53. Supplier means any registered person entitled to fill order forms pursuant to Sec. 1305.08 of the regulations.
- 54. <u>Ultimate User</u> means a person who has lawfully obtained, and who possesses, a Controlled Substance for his own use or for the use of a member of his household or for an animal owned by him or member of his household.

B. LIST I CHEMICALS

Definitions Relating To List I Chemicals (Reference is made to Sec. 1300.01 Code of Federal Regulations, Food and Drugs 21 Part 1300 to End, Revised as of April 1, 2000) and the Controlled Substances Act.

- 1. Act means the Controlled Substances Act, as amended (84 Stat. $\overline{1242}$; 21 U.S.C. 801) and/or the Controlled Substances Import and Export Act, as amended (84 Stat. 1285; 21 U.S.C. 951) as amended.
- 2. Administration means the Drug Enforcement Administration.
- 3. Administrator means the Administrator of the Drug Enforcement Administration. The Administrator has been delegated authority under the Act by the Attorney General (28 CFR 0.100).
- 4. <u>Broker and trader</u> mean any individual, corporation, corporate division, partnership, association, or other legal entity which assists in arranging an international transaction in a listed chemical by

- (a) Negotiating contracts;
- (b) Serving as an agent or intermediary; or
- (c) Fulfilling a formal obligation to complete the transaction by bringing together a buyer and seller, a buyer and transporter, or a seller and transporter, or by receiving any form of compensation for so doing.
- 5. Chemical export means transferring ownership or control, or the sending or taking of threshold quantities of listed chemicals out of the United States (whether or not such sending or taking out constitutes an exportation within the meaning of the Customs and related laws of the United States).
- 6. Chemical exporter is a regulated person who, as the principal party in interest in the export transaction, has the power and responsibility for determining and controlling the sending of the listed chemical out of the United States.
- 7. Chemical import means with respect to a listed chemical, any bringing in or introduction of such listed chemical into either the jurisdiction of the United States or into the Customs territory of the United States (whether or not such bringing in or introduction constitutes an importation within the meaning of the tariff laws of the United States).
- 8. <u>Chemical importer</u> is a regulated person who, as the principal party in interest in the import transaction, has the power and responsibility for determining and controlling the bringing in or introduction of the listed chemical into the United States.
- 9. Chemical mixture means a combination of two or more chemical substances, at least one of which is not a listed chemical, except that such term does not include any combination of a listed chemical with another chemical that is present solely as an impurity or which has been created to evade the requirements of the Act.
- 10. Customs territory of the United States means the several States, the District of Columbia, Puerto Rico.
- 11. Encapsulating machine means any manual, semiautomatic, or fully automatic equipment which may be used to fill shells or capsules with any powdered, granular, semi-solid, or liquid material.
- 12. Established business relationship with a foreign customer means the regulated person has exported a listed chemical at least once within the past six months, or twice within the past twelve months to a foreign manufacturer, distributor, or end user of the chemical that has an established business in the foreign country with a fixed street address. A person or

business which functions as a broker or intermediary is not a customer for purposes of this definition. The term also means that the regulated person has provided the Administration with the following information in accordance with the waiver of 15-day advance notice requirements of Sec. 1313.24 of the regulations:

- (a) The name and street address of the chemical exporter and of each regular customer;
- (b) The telephone number, telex number, contact person, and where available, the facsimile number for the chemical exporter and for each regular customer;
- (c) The nature of the regular customer's business (i.e., importer, exporter, distributor, manufacturer, etc.), and if known, the use to which the listed chemical or chemicals will be applied;
- (d) The duration of the business relationship;
- (e) The frequency and number of transactions occurring during the preceding 12-month period;
- (f) The amounts and the listed chemical or chemicals involved in regulated transactions between the chemical exporter and regular customer;
- (g) The method of delivery (direct shipment or through a broker or forwarding agent); and
- (h) Other information that the chemical exporter considers relevant for determining whether a customer is a regular customer.
- 13. Established record as an importer means that the regulated person has imported a listed chemical at least once within the past six months, or twice within the past twelve months from a foreign supplier. The term also means that the regulated person has provided the Administration with the following information in accordance with the waiver of the 15-day advance notice requirements of Sec. 1313.15 of the regulations:
 - (a) The name, DEA registration number (where applicable), street address, telephone number, telex number, and, where available, the facsimile number of the regulated person and of each foreign supplier; and
 - (b) The frequency and number of transactions occurring during the preceding 12 month period.
- 14. Hearing means any hearing held for the granting, denial, revocation, or suspension of a registration pursuant to

- sections 303, 304, and 1008 of the Act (21 U.S.C. 823, 824 and 958).
- 15. International transaction means a transaction involving the shipment of a listed chemical across an international border (other than a United States border) in which a broker or trader located in the United States participates.
- 16. <u>Jurisdiction of the United States</u> means the customs territory of the United States, the Virgin Islands, the Canal Zone, Guam, American Samoa, and the Trust Territories of the Pacific Islands.
- 17. <u>Listed chemical</u> means any List I chemical or List II chemical.
- 18. <u>List I chemical</u> means a chemical specifically designated by the Administrator in Sec. 1310.02(a) of this chapter that, in addition to legitimate uses, is used in manufacturing a Controlled Substance in violation of the Act and is important to the manufacture of a Controlled Substance.
- 19. List II chemical means a chemical, other than a List I chemical, specifically designated by the Administrator in Sec. 1310.02(b) of this chapter that, in addition to legitimate uses, is used in manufacturing a Controlled Substance in violation of the Act.
- 20. Name means the official name, common or usual name, chemical name, or brand name of a substance.
- 21. Person includes any individual, corporation, government or governmental subdivision or agency, business trust, partnership, association, or other legal entity.
- 22. Readily retrievable means that certain records are kept by automatic data processing systems or other electronic or mechanized recordkeeping systems in such a manner that they can be separated out from all other records in a reasonable time and/or records are kept on which certain items are asterisked, redlined, or in some other manner visually identifiable apart from other items appearing on the records.
- 23. Register and registration refer only to registration required and permitted by sections 303 or 1007 of the Act (21 U.S.C. 823 or 957).
- 24. Registrant means any person who is registered pursuant to either section 303 or section 1008 of the Act (21 U.S.C. 823 or 958).
- 25. Regular customer means a person with whom the regulated person has an established business relationship for a specified listed chemical or chemicals that has been reported

- to the Administration subject to the criteria established in Sec. 1300.02(b)(12).
- 26. Regular importer means, with respect to a listed chemical, a person that has an established record as an importer of that listed chemical that is reported to the Administrator.
- 27. Regulated person means any individual, corporation, partnership, association, or other legal entity who manufactures, distributes, imports, or exports a listed chemical, a tableting machine, or an encapsulating machine, or who acts as a broker or trader for an international transaction involving a listed chemical, tableting machine, or encapsulating machine.

28. Regulated transaction means:

- (a) A distribution, receipt, sale, importation, or exportation of a listed chemical, or an international transaction involving shipment of a listed chemical, or
- (b) if the Administrator establishes a threshold amount for a specific listed chemical, a threshold amount as determined by the Administrator, which includes a cumulative threshold amount for multiple transactions, of a listed chemical, except that such term does not include:
 - (i) A domestic lawful distribution in the usual course of business between agents or employees of a single regulated person; in this context, agents or employees means individuals under the direct management and control of the regulated person;
 - (ii) A delivery of a listed chemical to or by a common or contract carrier for carriage in the lawful and usual course of the business of the common or contract carrier, or to or by a warehouseman for storage in the lawful and usual course of the business of the warehouseman, except that if the carriage or storage is in connection with the distribution, importation, or exportation of a listed chemical to a third person, this paragraph does not relieve a distributor, importer, or exporter from compliance with parts 1309, 1310, and 1313 of this chapter;
 - (iii) Any category of transaction or any category of transaction for a specific listed chemical or chemicals specified by regulation of the Administrator as excluded from this definition as unnecessary for enforcement of

the Act;

- (iv) Any transaction in a listed chemical that is contained in a drug that may be marketed or distributed lawfully in the United States under the Federal Food, Drug, and Cosmetic Act unless
 - The drug contains ephedrine or its salts, optical isomers, or
 - The Administrator has determined pursuant to the criteria in 1310.10 that the drug or group of drugs is being diverted to obtain the listed chemical for use in the illicit production of a Controlled Substance; and
 - The quantity of ephedrine or other listed chemical contained in the drug included in the transaction or multiple transactions equals or exceeds the threshold established for that chemical.
- (v) Any transaction in a chemical mixture listed in Sec. 1310.13 of this chapter.
- (vi) A distribution, importation, or exportation of a tableting machine or encapsulating machine except that such term does not include a domestic lawful distribution in the usual course of business between agents and employees of a single regulated person; in this context, agents or employees means individuals under the direct management and control of the regulated person.
- Retail distributor means a grocery store, general merchandise store, drug store, or other entity or person whose activities as a distributor relating to drug products containing pseudoephedrine, phenylpropanolamine, or ephedrine are limited almost exclusively to sales for personal use, both in number of sales and volume of sales, either directly to walkin customers or in face-to-face transactions by direct sales. For the purposes of this paragraph, sale for personal use means the distribution of below-threshold quantities in a single transaction to an individual for legitimate medical use. Also for the purposes of this paragraph, a grocery store is an entity within Standard Industrial Classification (SIC) code 5411, a general merchandise store is an entity within SIC codes 5300 through 5399 and 5499, and a drug store is an entity within SIC code 5912.
- 30. Tableting machine means any manual, semi-automatic, or fully

automatic equipment which may be used for the compaction or molding of powdered or granular solids, or semi-solid material, to produce coherent solid tablets.





III. POWER OF ATTORNEY FOR EXECUTING A DEA APPLICATION



IV. RECEIVING AND DOCUMENTING RECEIPT OF CONTROLLED SUBSTANCE MEDICATIONS



V. RECEIVING OF CONTROLLED SUBSTANCES



VI. SUSPICIOUS ORDER MONITORING

PURPOSE: To provide for monitoring of all Controlled Substances orders so as to detect suspicious orders.

PROCEDURE:

- 1. All orders containing Controlled Substances are reviewed and verified for order quantity and size to not exceed the determined order history threshold. Any order exceeding the threshold is immediately forwarded to the department manager for further investigation.
- 2. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.
- A review is performed to determine the legitimacy of the order. Appropriate documentation of the review is maintained on file.
- 4. Any order which is determined to be suspicious will be immediately reported to the corporate office, who will notify the local DEA Field Division Office of the Administration.
- 5. If a suspicious order is reported to Corporate, the Corporate Government Affairs will determine whether to "ship" or "do not ship".
- 6. All discussions, investigations and reports will be maintained in the file designated "Suspicious Orders".

VII. REGISTRATION VERIFICATION



VIII. DELIVERY OF CONTROLLED SUBSTANCES AND SELECTION OF COMMON OR CONTRACT CARRIERS





IX. DISTRIBUTION OF CONTROLLED SUBSTANCES





X. HANDLING AND RECORDS FOR UNSOLICITED RETURNS



DEA REGULATORY GUIDELINE XI. DISPOSAL OF CONTROLLED SUBSTANCES









XIII. REPORTING THEFT OR LOSS OF CONTROLLED SUBSTANCES









XV. CONDUCTING INVENTORIES



XVI. MAINTAINING ACCURATE RECORDS-FILING AND MAINTENANCE



DEA REGULATORY GUIDELINE XVII. CENTRAL RECORDS





XVIII (A). CONTROLLED SUBSTANCE SECURITY: PHYSICAL SECURITY

XVIII (B). CONTROLLED SUBSTANCE SECURITY: ELECTRONIC ALARMS



XVIII(C). CONTROLLED SUBSTANCE SECURITY: ACCESS CONTROL



XIX. INTERNAL AUDITS FOR SCHEDULE III, IV AND V CONTROLLED SUBSTANCES



XX. POLICY REVIEW AND REVISION AND ADMINISTRATIVE ACTIONS



DEA REGULATORY GUIDELINE XXI. HOW TO HANDLE A DEA INSPECTION















XXII. COORDINATION WITH REGULATORY AND ENFORCEMENT AGENCIES



XXIII. STAFF TRAINING



XXIV. LIST I CHEMICALS









DEA REGULATORY GUIDELINE XXV. VISITOR CONTROLS



XXVI. ARCOS





XXVII. FREIGHT FORWARDING



